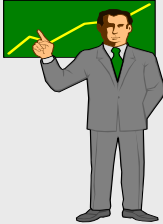


BENEFITS OF AUDITING THE QUALITY MANAGEMENT SYSTEM

Speaking of auditing!



- Assured of good business practices
- Means of determining effectiveness of the QMS
- Ensure customer & outside requirements met
- Add discipline to QMS
- Help identify opportunities for improvement

There are several positive outcomes from an audit. Whether the audit is from an external source, such as a USDA audit, or an internal audit, the results are the same.

Audits are assurance that good business practices, as described in a quality standard, are maintained.

Audits also assess the effectiveness of the Quality Management System and ensure that customer and outside requirements are met.

They provide discipline to the QMS. Audits prevent procrastination of making the necessary improvements.

Most importantly, audits offer an opportunity for improvement.

The purpose of this Training presentation is to help you understand the reason and method of performing an internal audit.

PURPOSE OF AUDITS

- ✓ **Audits aim to establish, by unbiased means, factual information on some aspect of performance.**
- ✓ **Audits are performed as a safeguard against a deterioration in standards.**
- ✓ **Audits are performed to establish facts rather than faults.**




2

Audits and auditors perform service to a company. They are a way to establish information based on facts, not on suspicion, suggestion or assumption.

They are a good way to keep an organization on top of the quality system, rather than letting the system ravel at the edges.

Audits establish facts. They should never be directed toward an individual or group within the organization.

THE INTERNAL AUDIT



An internal audit:

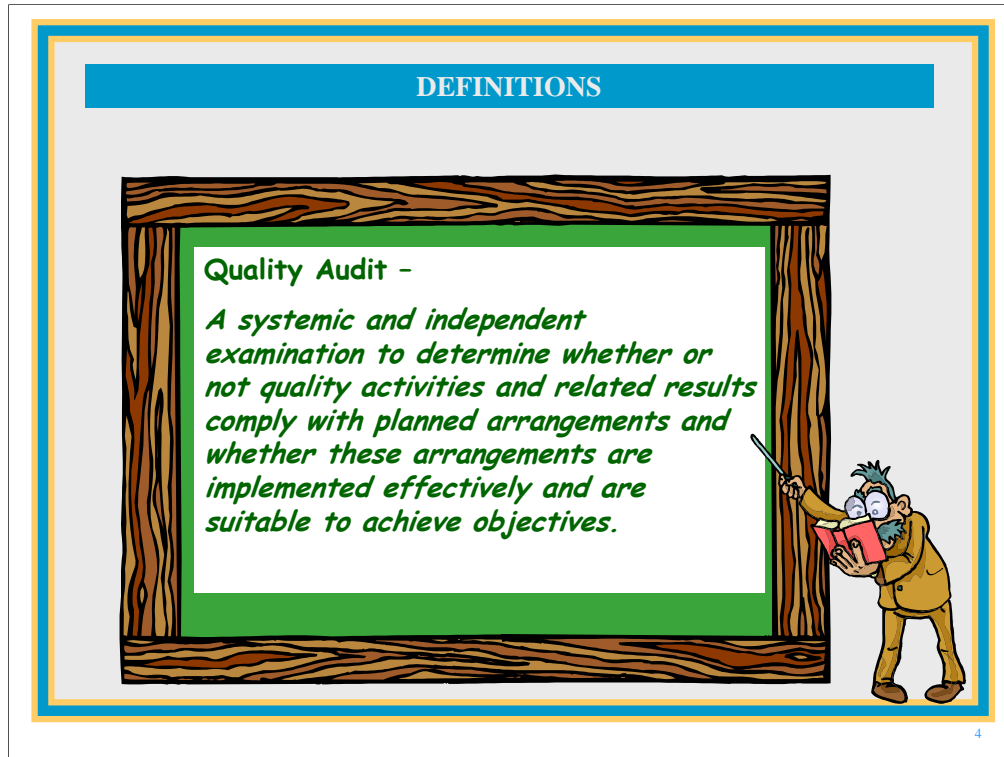
- ✓ Must be a planned activity and be documented.
- ✓ Focused only on the quality system.
- ✓ Must have specific requirements.
- ✓ Frequency must be determined by management.
- ✓ Must use objective evidence.
- ✓ The extent of follow-up verification depends on the noncompliance

Section 8.1 requires an Internal Audit

3

The list shown in this slide identifies the requirements for an internal audit. Section 8.1 requires a documented procedure for an internal audit.

The degree to which a nonconformance or noncompliance affects the quality system determines the degree of follow up required.



Before we continue the discussion, we need to be certain we understand one another. This slide and the three following it provide some important definitions.

What is a quality audit? See the definition above.

The key words are:

Systematic – the entire system must be audited

Independent – you can't audit your own work

Quality activities and related results – what you do and the results

Comply with planned arrangements – meet your plans and the quality standard


Implemented effectively and achieve objective – are you doing as planned, have you met your objectives?

DEFINITIONS

Quality Auditor -
A person who has the qualifications to perform audits.

Note: To perform a quality audit, the auditor must be authorized for that particular audit.

An auditor designated to manage a quality audit is called a "Lead Auditor."

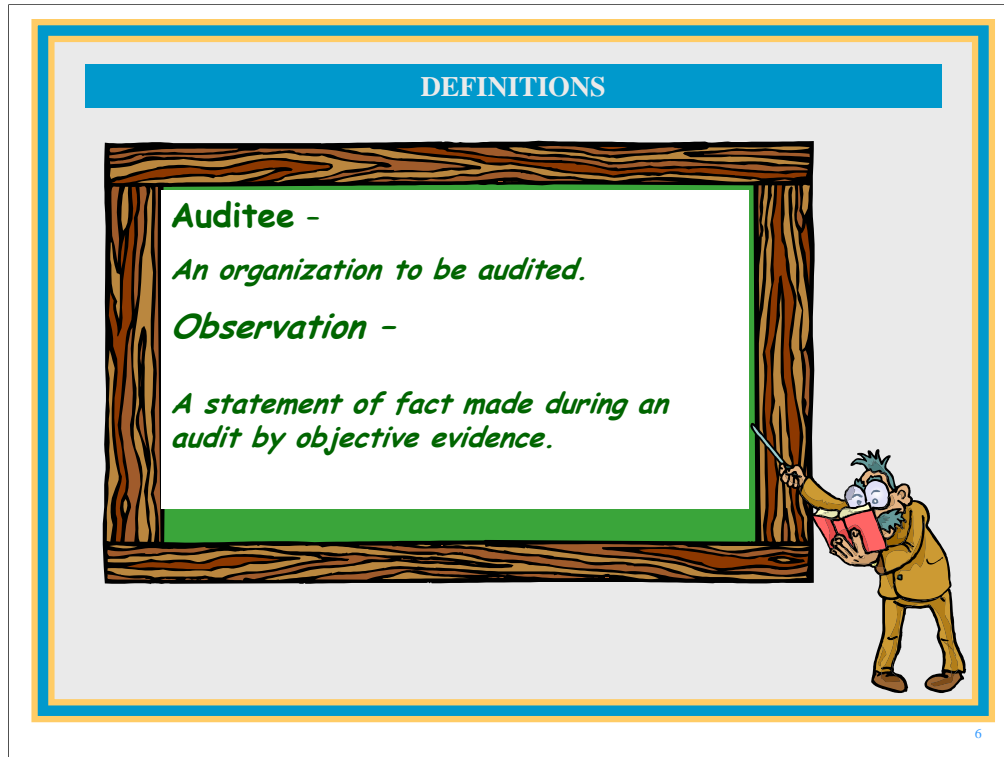
A cartoon character with a large nose, wearing a brown suit and glasses, is pointing with a stick at a white board. The board is framed by a thick, dark wood border. The character is holding a red book in his left hand.

5

What does it take to be an internal auditor?

You must understand the requirements of the quality standard.

You must have some introduction to auditing activities.



Two final definitions:

The auditee is someone inside your organization during an internal audit.

Your organization is the auditee when USDA performs the audit.

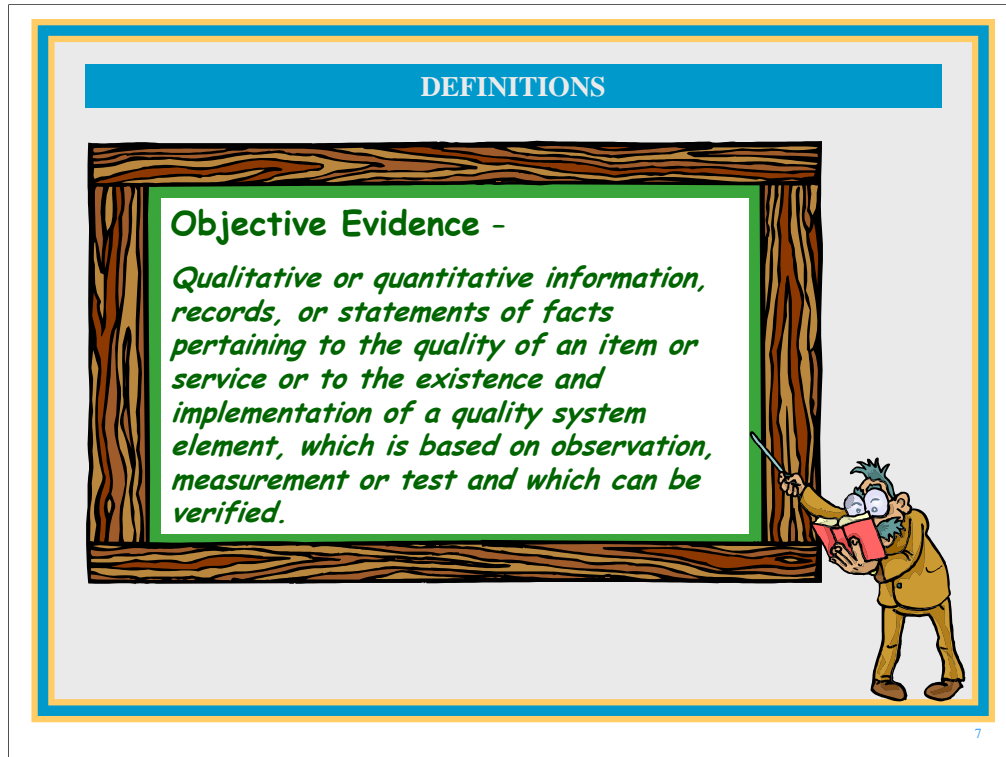
An observation is the statement made by the auditor regarding information he or she sees or hears. It is part of the audit report and is usually presented as evidence in a finding.

Following is an example of an audit finding.

Minor Non-Conformance

Section 3.3 b) requires a written procedure to establish controls needed for the identification, storage, protection, retention, disposition of all records. In examining the records it was noted that some records are not identified. They are kept on scraps of paper. Others are not easy to retrieve. It took 4 hours of searching to retrieve last month's records.

The objective evidence is that the records are written on scrap paper, and it took 4 hours to find last month's records.



Objective evidence may be obtained from an interview, but it must be substantiated by concurrence from one or more other people or by some kind of documentation.

Key words to the definition above:




Information, records, or statements of facts – must be based on evidence

Observation, measurement, or test which can be verified – again, must be based on tangible evidence.

WHAT IS AN AUDITOR ?

Qualifications for an auditor:

- Knowledge
- Training
- Independence
- Communication skills



8

An internal auditor must have knowledge of the quality standard to which he or she is auditing as well as knowledge of the business activities being audited. They also must have some training. Attending the GIPSA sponsored training sessions qualifies an individual to be an internal auditor.

They also must have independence – which means there can be no conflict of interest. You cannot audit your own work.

Auditors should also have good communications skills for this is the way audits are performed. Generally, questions are asked and information is sought to establish conformance.

WHAT IS AN INTERNAL AUDITOR ?

Role of the internal auditor

Look at the organization's systems, procedures and records and determine if they are in conformance with their policy, procedures, agreed standard and appropriate regulatory requirements.



9

Remember, and good auditor begins with the belief that the auditee is in conformance.

Auditing Skills and Communication

Auditor Personal Attributes

- Ethical
- Open-minded
- Diplomatic
- Observant
- Perceptive
- Versatile
- Tenacious
- Decisive, and
- Self-reliant



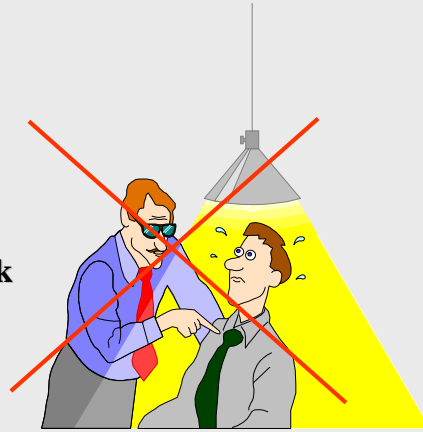
10

The above list is taken from ISO 19011, a quality standard for auditors and audit programs. They are representative of a PERFECT auditor. Since none of us are perfect, we should strive to adopt these characteristics and hope that we master some of them.

ROLE OF THE INTERNAL AUDITOR

Auditors are not:

- **Fault finders**
- **Rock throwers**
- **Nit-pickers**
- **An interrogation task force**
- **Dishonest**



11

Auditors are not looking to find fault or to place blame. Above all they must be honest.

EVALUATING MANAGEMENT SYSTEM'S EFFECTIVENESS

**Audits verify the effectiveness of the
Quality Management System.**

**Auditors do not audit people, only the
Quality Management System.**



12

Is the standard requirement being met? Are the legal requirements being met?

An audit is not a test of how someone does his or her job.

PLANNING THE AUDIT

- **Agenda**
- **Review Information**
- **Date and Time**
- **Work Hours**
- **Distribution of Work**

13

Audits are formal activities and should be carefully planned. The above list gives broad parameters for an audit plan.

PLANNING THE AUDIT

Working documents needed to facilitate the audit:

- **Forms for documenting objective evidence;**
- **Forms for documenting audit findings;**
- **Procedures to be followed;**
- **Checklist format;**
- **Meeting topics; and**
- **Meeting record format.**

14

In addition to the items listed in the previous slide, some of these documents will be used. Not all may be applicable to every audit.

THE AUDIT PLAN

The audit plan details a particular audit and includes:

- **The organization to be audited**
- **Purpose and scope**
- **Audit personnel**
- **Activities to be audited**
- **Organization/personnel that are to be audited**
- **Applicable document/records**
- **Audit checklist**
- **Requirements for reporting results**

15

A formal document must be created, The Audit Plan. This is the blueprint used by auditors to ensure that the audit is completed properly. An audit plan should be part of the Documented Procedure for performing Internal Audits.

AUDIT PLAN

The audit plan (see ISO 19011 6.4.1)

- **Audit objectives;**
 - **Audit criteria and reference documents;**
 - **Audit scope (includes units and processes to be audited);**
 - **Dates and places where on-site activities are conducted;**
 - **Time and duration of on-site activities, including meetings;**
 - **Roles and responsibilities of audit team members**
-continued**

16

ISO 19011 expands the requirements. These slides are presented as information. OSPs should review the slides to see if they wish to expand their Audit Plan to include any of these topics.

OSP with multiple sites will benefit from a more expansive audit plan such as this.

AUDIT PLAN

The audit plan (see ISO 19011 6.4.1)

- Allocation of resources to critical areas;
- Identification of auditee's representative;
- Audit report topics;
- Logistic arrangements;
- Matters related to confidentiality; and
- Any follow-up actions.

17

This is a continuation of the above slide.

AUDIT SCHEDULE	
Typical Daily Audit Schedule	
Schedule for July 17, 2005	
8:00 - 8:30	Auditor Preparation
8:30 - 9:00	Facility Tour
9:00 - 9:30	Opening Meeting
9:30 - 10:30	Management Review
10:30 - 11:30	Control of Quality Records
11:30 - 12:30	Working Lunch
12:30 - 2:30	Product Realization
2:30 - 4:30	Auditor Work Time
4:30 - 5:00	Closing Meeting

Auditors would be wise to set a schedule. This keeps the audit on track and prevents auditors from getting too deep into details when it is unnecessary. However, the schedule is a guideline. Auditors must be flexible and able to change the schedule if their original plan is not accurate. Some things take less time than expected and others take more time than anticipated.

Audits generally begin with an opening meeting to discuss the audit, and they end with a closing meeting to discuss the audit findings.

Audit findings are not secrets to be hoarded until the closing meeting. When an auditor believes he or she has identified a non-conformance, the auditee should be informed and allowed to provide additional information if possible.

AUDIT CHECKLIST

- **Each auditor prepares own**
- **Audit objectives**
- **Audit criteria**
- **Sample of activities to assess**
- **Time available for the audit**
- **Information reviewed**

19

Auditors need a checklist to know what questions to ask and which documents and records to observe. The checklist can be as simple or as elaborate as meets your needs; however, the entire system must be audited each year.

TYPES OF AUDITS

Elements	Office	Lab	Off site lab
1	Vertical		
2		Vertical	
3			Vertical
4			
5			

Elements	Office	Lab	Off site lab
1	Horizontal		
2		Horizontal	
3			Horizontal
4			
5			

20

Audits may be broken up into several small parts. There are two recognized ways to audit by segment:

- 1) Audit individual areas of your organization for all applicable requirements (a vertical audit) or
- 2) Audit all areas of the company using one or more processes or Elements of the standard (a horizontal audit).

DEVELOP GOOD AUDITING SKILLS

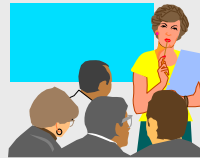
- **avoid leading, multiple, & trick questions**
- **listen intently**
- **be observant & take notes**
- **try to establish root cause of deficiencies**
- **actually witness & document objective evidence**
- **avoid giving advice**
- **remain calm, courteous, polite, professional & firm**

21

Above listed are some good auditing skills. It is important to take notes because they become the record of the internal audit. When USDA audits your facility, the auditors will ask to see the Internal Audit records.

COLLECTING EVIDENCE..Communication

- **Communicate clearly.**
- **Be open minded.**
- **Be aware of biases.**
- **Ask questions in regard to the QMS.**
- **Do not make assumptions.**
- **Lead auditors should rely on the audit team.**



22

Be certain to explain what you are looking for. One way to do that is to read the requirement from the QMS, and then ask for information supporting conformance. Another way is to lead the auditee into providing the information you are seeking by asking leading and probing questions.

Auditors must be open minded and leave biases and prejudice behind. If you feel that you simply cannot be open minded, it is appropriate to dismiss yourself from the audit.

Questions should focus on the quality standard or the QMS documentation, including the quality manual and procedures.

Never make assumptions, be certain that evidence supports all conclusions.

If you are a large organization and require a lead auditor, that person should rely on the audit team to provide information.

COLLECT EVIDENCE..THE INTERVIEW

(ISO 19011, 6.5.4)

- **Be prepared.**
- **Be aware of process you are auditing.**
- **Ask open ended questions.**
- **Ask probing questions.**



23

Prior to interviewing an auditee, be certain that you know which process or processes you are following through the organization. Prepare some questions in advance to ensure that you have a basis for the audit. Also, be prepared to leave the prepared questions to follow up on topics not covered.

Ask probing and open-ended questions.

BASIC QUESTION TYPES

- **Open Ended Questions**
- **Closed ended Questions**
- **Probing Questions**
- **Leading/Loaded Questions**

24

Following are different types of questions you might ask.

Open-ended questions lead the recipient to a long and detailed response.

“Will you please explain how you do this SOP?”

Closed-ended questions can be answered with one word, usually “yes” or “no”.

“Do you know how to do this SOP?”

Probing Questions are open ended, but also lead to a conclusion.

“Will you please tell me how the accurate performance of the SOP adds to the overall quality of the organization?”

Leading or loaded questions provide the answer or trigger an expected response.

“You know how to perform this SOP, don’t you?”

SOME QUESTIONS TO ASK THE STAFF

Are these open ended or closed ended?

- 1 Are things being done the way you documented them?**
- 2 Is the department manager and staff following their own procedures and work instructions?**
- 3 Is your system effective?**
- 4 Are you meeting your quality objectives?**
- 5 Is the Quality Policy a reality?**
- 6 What is your responsibility and authority?**
- 7 In what way does the quality policy effect what you do?**
- 8 What feedback do you receive about your performance?**
- 9 When problems arise, what do you do about them?**

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Try to determine which of these questions are closed ended.

Try to rephrase them to be open-ended and/or probing questions.

COLLECTING EVIDENCE

- **Write down the information as you conduct the audit.**
- **Keep all of your notes together.**



26

Auditors must keep audit records to verify that the Internal Audit was performed and to assure that the facts are correct. Sometimes our memories play tricks on us or fail to recall all the pertinent information we collect. Keep all the notes together while performing the audit. At the audit conclusion, collect the notes from all auditors for a complete audit record.

COLLECTING EVIDENCE

Documentation to audit:

- Policies
- Procedures
- Work Instructions
- Records
- External Documents



27

Above is a good list of documentation you will audit during an internal audit. Not all parts of your organization will have all of the items listed here. Use this list as a guideline while preparing your audit plan.

METHODS FOR IMPROVING AUDITING SKILLS

Ask questions instead of giving direct orders, if you are the audit team leader.

There are two things that every person in the world appreciates...

**...to be asked.
...to be thanked.**

28

Don't forget to be polite.

WHAT ARE AUDIT FINDINGS ?

- An observation is a positive, negative or neutral fact that is supported by objective evidence.
- A nonconformity is the non-fulfillment of a requirement.
- An audit finding is a written statement or conclusion describing a nonconformity. It includes:
 - the requirement, as it is stated in the quality standard, or regulation and
 - the observation which provides evidence that the standard or regulation is not being met.

RECORD ALL AUDIT FINDINGS!

29

The audit report should include positive observations about what is going right in the organization. Occasionally, groups or even individuals are singled out for outstanding performance.

The report audit must include “audit findings” which are negative statements of nonconformance or noncompliance. Findings must be based on objective evidence and examples of the nonconformity must be provided.

Audit finding in an internal audit become preventive or corrective actions.

COMPLETION

- **All nonconformities are addressed.**
- **All corrective actions implemented.**
- **All corrective actions evaluated as effective.**
- **Audit completed.**



30

An audit isn't complete until all nonconformance or noncompliance has been addressed by the appropriate part of the organization. Corrective action must be identified, taken and the effectiveness verified.

Corrective action should be verified by the internal auditor. Only when the nonconformance or noncompliance is "closed out" is the audit completed.

THE GOLDEN RULES OF AUDITING

- ✓ **Be prepared**
- ✓ **Retain an open mind**
- ✓ **Be professional**
- ✓ **Do not waste time**
- ✓ **Present a true and fair view**



Calm, Courteous, Professional, Polite & Firm

31

Internal audits are an opportunity to practice professionalism and make a real difference in your organization. Audits and auditors provide management with a ways to make improvements, save money, and boost morale.